

EXHIBIT B2

Terence J. Colgan, M.D.

1 ---EXHIBIT NO. 10: A paper co-authored
2 by Dr. Iakovlev, titled Degradation of
3 polypropylene in vivo: A microscopic analysis of
4 meshes explanted from patients, published in
5 Journal of Biomedical Materials Research, February
6 2017, Volume 105B, Issue 2.

7 BY MR. RESTAINO:

8 Q. Okay. Now, Dr. Colgan, I believe
9 you testified that you read this paper after its
10 publication.

11 Is that correct?

12 A. I read it after its electronic
13 publication, yes.

14 Q. And the electronic publication was
15 in August of 2015?

16 A. Yes.

17 Q. And when you read this paper --
18 well, with it being published in the Journal of
19 Biomedical Materials Research, do you subscribe to
20 this journal?

21 A. I do not.

22 Q. And why did you read this paper
23 when it came out online or electronically in 2015?

24 A. It was brought to my attention by
25 Andrew Snowden--

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1 Q. Okay.

2 A. --after our discussions of late
3 2016.

4 Q. Okay. And once you read the
5 paper, did you have criticisms of the methodology
6 and/or conclusions in the paper?

7 A. I did.

8 Q. And at that time, did you attempt
9 to contact the member of your department,
10 Dr. Iakovlev, and discuss your criticisms?

11 A. I did not.

12 Q. Is there a reason why not?

13 A. It was for two reasons at least.

14 (1), it's not my custom to contact
15 colleagues if I disagree with their paper.

16 And (2) is, it was a published paper
17 and it would be unlikely to come to any useful
18 conclusion, short of retracting the entire article.

19 Q. And is it your understanding that
20 being published in the Journal of Biomedical
21 Materials Research Part B: Applied Biomaterials,
22 it is a peer-reviewed paper?

23 A. I would expect it to be. I'm not
24 familiar with its editorial board.

25 Q. In August of 2015, Richard Hegele,

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1 H-e-g-e-l-e, MD, was the Chair of the University of
2 Toronto Department of Pathology.

3 Is that correct?

4 A. Yes.

5 Q. Did you bring your criticisms of
6 this paper to your department chair, indicating
7 that a member of the department had published
8 something that you disagreed with?

9 A. No, I did not.

10 Q. And currently, it's Avrum,
11 A-v-r-u-m G-o-t-l-i-e-b, Gotlieb is...?

12 A. Actually, he has stepped down.

13 There's a new chair now. Her name is
14 Rita Kandel, K-a-n-d-e-l. She took up her position
15 as of April 1st, I believe it was.

16 Q. With the current chair and/or the
17 interim chair, Dr. Gotlieb, have you ever
18 approached them with your criticisms of

19 Dr. Iakovlev's paper?

20 A. I did not.

21 Q. When it came out, did you --

22 A. Can I elaborate on that answer?

23 Q. Of course.

24 A. There is a university and
25 departmental promotions and appointments committee

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1 I used.

2 Q. Okay.

3 A. As I recall, I believe I used the
4 terms "vaginal mesh" and "mesh", and whether this
5 paper was brought up or not, I can't recall.

6 Q. Fair enough.

7 At any time since this paper was
8 published online and you were writing your expert
9 report and preparing for today's deposition, have
10 you gone online to see how many papers have cited
11 Dr. Iakovlev's paper?

12 A. No, I have not.

13 MR. DAVIS: Object to the form.

14 BY MR. RESTAINO:

15 Q. As you sit here today, do you have
16 an understanding of how many times this paper has
17 now been cited in the peer-reviewed medical
18 literature?

19 A. I have not inquired about that.

20 Q. As you sit here today, do you know
21 if anyone has written any letter to the editor of
22 the journal, criticizing Dr. Iakovlev's methodology
23 and/or work?

24 A. I don't know of any such letter.

25 Q. Have you had any discussions with

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1 surgical pathology material is
2 derived from living human patients,
3 potential confounding variables can
4 rarely be fully controlled or
5 eliminated."

6 Did I read that correctly?

7 A. Yes, you did.

8 Q. And that is one of your criticisms
9 of Dr. Iakovlev's published paper; that it is, in
10 fact, an observational study; correct?

11 A. Yes. You could call it a
12 "criticism". Perhaps a better word would be
13 "limitation".

14 Q. Okay. Do you feel that that
15 limitation decreases the value of the study?

16 A. Since Dr. Iakovlev has gone on to
17 try and draw correlations between the surgical
18 pathologic findings and symptomatology, yes.

19 Q. Okay. Now if we could go back to
20 the Hill paper, the "Histopathology of excised
21 midurethral sling mesh", which is Exhibit 11.

22 A. Yes.

23 Q. This is also an observational
24 study, is it not?

25 A. Yes, it is.

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1 Q. If you look at "Methods" in the
2 abstract, they describe this as:

3 "...a retrospective
4 case-control study of women who
5 underwent excision of midurethral
6 sling mesh between 2008 and 2013."

7 Correct?

8 A. Mm-hmm. Correct.

9 Q. Dr. Iakovlev's paper is a
10 retrospective study, also; correct?

11 A. Correct.

12 Q. Now, the utilizing your language
13 in your expert report that we just read from, the
14 same "potential confounding [factor] variables
15 which can rarely be fully controlled or
16 eliminated", as you apply to Dr. Iakovlev's paper,
17 also apply to the Hill paper which is your
18 reference 10 that you are relying upon for your
19 expert opinion; correct?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: The Hill paper did go
22 further, though, and had good clinical data to put
23 together with their histopathologic obligations.

24 BY MR. RESTAINO:

25 Q. And you understand that there are

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1 the Hill paper did not have access to all of the
2 index surgical operative reports, did they?

3 A. I can't recall that.

4 Q. Would that be important to you?

5 A. Sorry. Can you repeat that
6 question again?

7 Q. The authors of the Hill paper did
8 not have access to all of the index surgical
9 operative reports; therefore, they had to rely upon
10 subject recall, as documented in the electronic
11 medical record, for some of the data.

12 And that is a weakness and source of
13 bias in a retrospective case-control study, is it
14 not?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: The... There are often
17 limitations in the amount of clinical data one can
18 obtain, either through a practical availability or
19 ethic board approval, but this doesn't change the
20 fact that they did get some clinical data which is
21 not present in Iakovlev's paper.

22 BY MR. RESTAINO:

23 Q. In fact, they were able to obtain
24 only 55 percent of the index surgical operative
25 reports, and without the index operative surgical

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1 report, the authors are -- the authors were unable,
2 in 45 percent of the cases, to analyze potential
3 risk factors that may have led to increased levels
4 of inflammation, including the date of the index
5 mesh placement, because there's acute inflammation
6 associated with surgery; correct?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: Acute inflammation is
9 usually seen upon initial insertion of the mesh,
10 yes.

11 BY MR. RESTAINO:

12 Q. And the type of mesh utilized;
13 there are different inflammatory responses
14 dependent upon the type of mesh utilized.

15 Would you agree?

16 A. I'm not an expert in the
17 examination of -- of mesh.

18 Q. And there's --

19 A. Research-wise.

20 Q. Forgive me. I'm sorry. I didn't
21 mean to interrupt.

22 And the other potential risk factor is
23 the surgical approach that was utilized; whether it
24 was transobturator or retropubic can make a
25 difference.

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1 and then subject to criticism by the general
2 scientific or medical community, then the
3 scientific method has been fulfilled, has it not?

4 A. But that was not the case here.

5 This case did not follow the scientific
6 method. It put forward a hypothesis and then
7 muddled the waters throughout the "Materials and
8 methods" and "Results" sections.

9 Q. The paper, in your opinion, did
10 that, but the scientific method employed by the
11 researchers are the thinking of an hypothesis, the
12 actual testing of the hypothesis, the actual
13 observation of results, the actual deduction of
14 conclusions, then writing the paper for peer
15 review.

16 That scientific method has been
17 fulfilled in this paper. It's just your criticism
18 of where they put the language; correct?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: They did attempt to write
21 a scientific paper.

22 BY MR. RESTAINO:

23 Q. And it was published in the
24 peer-reviewed medical literature?

25 A. It was published in a

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1 peer-reviewed journal.

2 MR. RESTAINO: Okay. Let's go ahead
3 and take our next break.

4 ---Recess at 11:04 a.m.

5 ---On resuming at 11:11 a.m.

6 BY MR. RESTAINO:

7 Q. Welcome back, Doctor.

8 A. Thank you.

9 Q. We could continue on page 14 of
10 your report, the section titled "Response to
11 Dr. Iakovlev's expert report".

12 You write:

13 "In the introduction of his
14 summary opinion, his expert report,
15 Dr. Iakovlev states that, 'The mesh
16 itself, as a foreign object, and the
17 body reaction to the mesh damaged
18 the tissues in a critical anatomical
19 location.'" [As read.]

20 Do you agree with that statement?

21 MR. DAVIS: Object to the form.

22 Do you mean, does he agree that
23 Dr. Iakovlev said that?

24 MR. RESTAINO: Let me rephrase that.
25 That's an excellent objection.

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1 disappear.

2 BY MR. RESTAINO:

3 Q. On page 14, right above the
4 section "Response to Dr. Iakovlev's Expert Report",
5 that one-sentence paragraph, you write:

6 "In this paper Dr. Iakovlev
7 concludes that the mechanism leading
8 to mesh-related complications is
9 unclear, through his statement,
10 '...the exact mechanisms of these
11 late complications are yet to be
12 understood, '."

13 Did I read that correctly?

14 A. Yes, you did.

15 Q. Now, in fact, if you turn to page
16 10 of Dr. Iakovlev's paper, there's a section on
17 the left column... Are you there, sir?

18 A. Yes.

19 Q. Okay. ...that says "Clinical
20 significance of polypropylene degradation".

21 Do you see that?

22 A. Yes.

23 Q. And in the second paragraph where
24 I believe you're attempting to quote from, he
25 writes:

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1 "The clinical descriptions
2 provided with the specimens
3 indicated that in many cases,
4 mesh-related complications develop
5 several years after mesh
6 implantation. The exact mechanisms
7 of these late complications are yet
8 to be understood, however factors
9 accumulating over time need to be
10 considered as primary contributors."

11 Did I read that correctly?

12 A. Yes, you did.

13 Q. That's not what you quoted in your
14 paper.

15 A. I quoted --

16 MR. DAVIS: Object to form.

17 THE WITNESS: I quoted partially. I
18 didn't put in the entire sentence.

19 BY MR. RESTAINO:

20 Q. Okay. Now, the medical literature
21 itself is replete with reports of mesh-related
22 complications developing several years after
23 implantation, is it not?

24 A. I have become aware of them.

25 Q. And that literature includes both

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1 incontinence who have recently
2 reaffirmed their support for the use
3 of polypropylene mid-urethral
4 slings."

5 Is that your opinion?

6 A. Yes.

7 Q. Have you ever seen or heard
8 Dr. Iakovlev write or say that in his opinion,
9 these mesh devices should be taken off the market?

10 A. No, I have not heard him say that.

11 Q. Does he state that anywhere in his
12 expert report?

13 A. Not that I'm aware of.

14 Q. In fact, in his papers and in his
15 expert report, as a pathologist, Dr. Iakovlev
16 describes pathology which, as we started off the
17 deposition by saying, is the study of disease
18 hopefully in order to prevent or treat disease;
19 correct?

20 A. Correct.

21 Q. So in support of his opinion, you
22 reference in your expert report, the May 2017
23 position paper by the Royal Australian and New
24 Zealand College of Obstetricians and Gynecologists
25 known at RANZCOG, all capital, R-A-N-Z-C-O-G.

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1 Did I read that correctly?

2 A. Yes, you did.

3 Q. And you describe this as an
4 authoritative and independent body; correct?

5 A. Correct.

6 Q. How many members belong to
7 RANZCOG?

8 A. I do not practice in Australia or
9 in New Zealand.

10 Q. Do you know if there's less than a
11 hundred?

12 A. Do I know -- sorry. Is that a
13 statement or a question?

14 Q. A question.

15 Do you know if there's less than 100
16 members of the Association?

17 A. I would be surprised. I mean, if
18 it encompasses obstetricians and gynecologists in
19 that country, I would expect there would be
20 hundreds.

21 Q. Do you know if there is less than
22 a thousand?

23 A. I do not.

24 Q. Do you know if they publish a
25 monthly journal?

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1 A. I believe they do.

2 Q. Have you ever attended any of
3 their annual meetings?

4 A. No. I'm not an obstetrician or
5 gynecologist.

6 Q. Do you know if they hold an annual
7 meeting?

8 A. I do not.

9 Q. And in preparation for writing
10 your expert report, have you ever read any other
11 paper or position paper by this organization?

12 A. I am acquainted with the practice
13 of gynecologic pathology in that area--

14 Q. What --

15 A. --and have -- and have read some
16 papers from their journal.

17 Q. In your expert opinion, what is it
18 about this organization that makes it

19 "authoritative"?

20 A. I believe that the Australian and
21 New Zealanders are well-respected with to their
22 practice of medicine.

23 Q. Do you have any objective basis
24 for that statement?

25 A. Only 25 years' experience.

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1 Q. That would be anecdotal. Would
2 you agree?

3 A. Yes.

4 Q. Okay. In this position paper, do
5 they describe, at all, degradation of polypropylene
6 mesh?

7 A. In reference to your last
8 question, they did use methodology which is widely
9 accepted using "Grade A" and references.

10 Q. Okay. In utilizing the -- that --

11 A. Methods for guideline development.

12 Q. In the paper, do they describe
13 "degradation"?

14 A. I haven't read it in the last
15 three months. I would have to reread it to answer
16 that question.

17 Q. Do you recall if they describe
18 "foreign body reaction" in the paper?

19 A. Again, the same answer.

20 Q. In relying upon this paper which
21 you describe as from being (sic) an "authoritative"
22 organization, where do they differ or where do they
23 disagree with Dr. Iakovlev if they -- I will
24 represent to you, a word search does not come up
25 with "degrade" or "degradation" or nor does it come

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1 Q. Do you not believe that Dr. "I"
2 presents, with his coworkers, his basis for his
3 beliefs regarding the cause of pain that patients
4 experience with mesh?

5 A. I believe he has attempted that,
6 yes.

7 Q. And as a pathologist, the study of
8 the cause of disease is an important factor;
9 correct?

10 A. When pursued in a scientifically
11 valid fashion, yes.

12 Q. And have you -- you criticize his
13 paper that we have been discussing regarding the
14 language of -- the placement of certain language.

15 Have you reviewed all of his papers on
16 transvaginal mesh?

17 A. I have not.

18 Q. Now, if I can find it... Ah, yes.

19 On page 16, there's a full paragraph,
20 the very first full paragraph, and you indicate
21 there that:

22 "Dr. Iakovlev fails to
23 acknowledge the low complications
24 from mesh devices yet he himself
25 co-authored a review article that

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1 plate under sensitive mucosa' states
2 unequivocally that '...the mucosa is
3 under risk for pain if it becomes
4 compressed against the mesh-scar
5 plate'. No evidence is presented to
6 support this hypothesis."

7 Is that correct?

8 A. That is correct.

9 Q. But that was Component 9.

10 You didn't put in the report to the
11 judge Component 8. And in Component 8, he actually
12 writes about innervation of the female genital
13 organs:

14 "Furthermore, the female
15 genital area has much higher nerve
16 density compared to the midline
17 anterior abdominal wall and the
18 groin. The scar inhabiting and
19 surrounding the transvaginal meshes
20 has the highest nerve density out of
21 all explanted surgical meshes I have
22 examined as a pathologist. Thus
23 placement of the vaginal mesh is
24 associated with higher risk for
25 chronic pain than the placement of

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1 the mesh for hernia repair, either
2 ventral or in the groin."

3 [As read.]

4 Did I read that correctly?

5 A. I accept that you did.

6 Q. And you did not include that in
7 your expert report?

8 A. I did not comment on every
9 component; this is correct, but it still does not
10 change my opinion on what I wrote under Component
11 9, that what he said about stiff, irregular
12 mesh-scar plate under sensitive mucosa is
13 speculation by a histopathologist based upon
14 histopathology alone.

15 Q. "Based on histopathology alone".

16 First, you studied general anatomy in
17 medical school, did you not?

18 A. Mm-hmm.

19 Q. And as --

20 --- (Court reporter appeals.)

21 THE WITNESS: Yes.

22 BY MR. RESTAINO:

23 Q. And as you rotated through your
24 gynecological and surgical residencies, you felt
25 living gynecological tissue; correct?

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1 Q. And in your search for writing
2 your expert opinion where, in your opinion, there's
3 little to no evidence that mesh contracts, you did
4 not find the paper "Vaginal mesh contraction"; do
5 you agree?

6 A. I must not have.

7 MR. RESTAINO: I have no further
8 questions.

9 MR. DAVIS: Okay.

10 MR. RESTAINO: How's that for timing?

11 MR. DAVIS: You did great.

12 Let's just take a break for a second.

13 ---Recess at 12:16 p.m.

14 ---On resuming at 12:20 p.m.

15 EXAMINATION BY MR. DAVIS:

16 Q. Dr. Colgan, as you know, I'm Paul
17 Davis. I have just a few follow-up questions.

18 I don't know if I wrote this down
19 accurately or not, but early on in your deposition,
20 in an answer to one of John's questions, I believe
21 I heard you say something to the effect that, 'I
22 did not hold myself out to be an expert in the
23 pathology of vaginal mesh.'

24 Whether -- do you recall saying
25 something to that effect?